Data Spaces Symposium
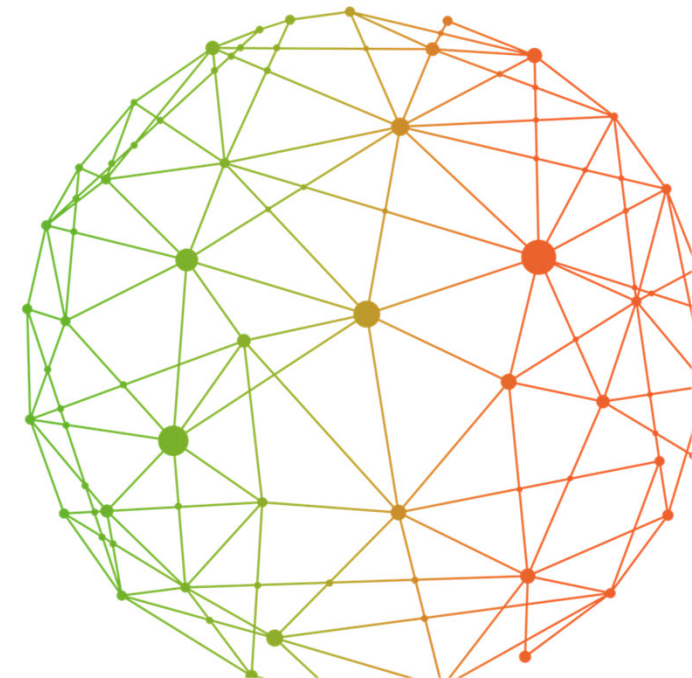
11:00

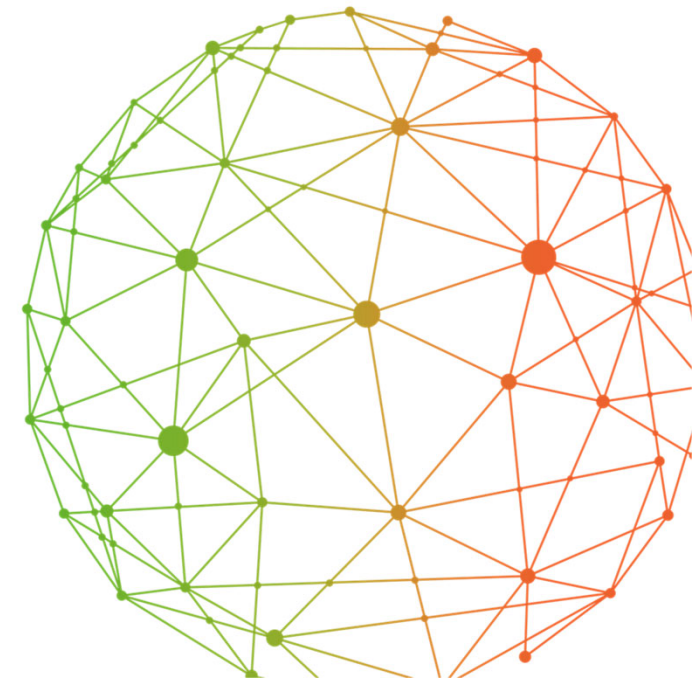## The future of healthcare: Unlocking value creation through data sharing

Domain session on healthcare data spaces

Data Spaces Symposium

EUCAIM – Building a Data-Driven Future for Cancer Care

Maciej Bobowicz
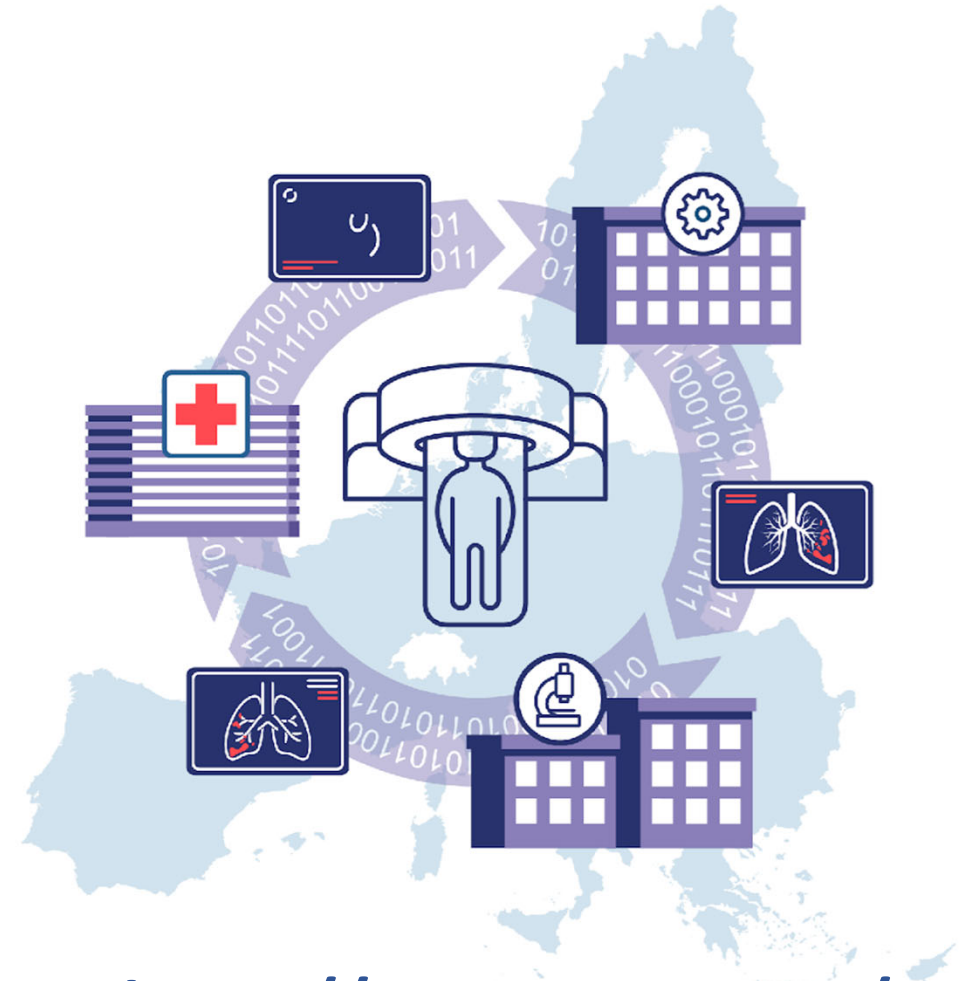
Technical implementations

Data User

Data discovery
(federated search via catalogue & explorer)

Permit application
(negotiator)

EUCAIM Access Committee

Data Preparation
(lightweight in the Atlas, negotiator and AAI)
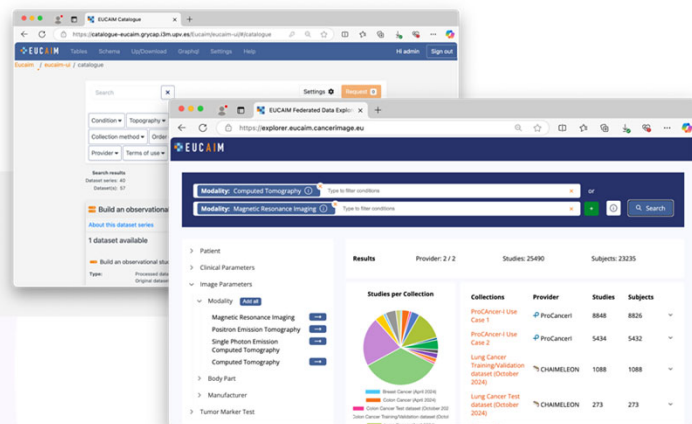
Data use
(@Reference nodes SPEs or Fed processing)

Researcher

Data provision
(@Reference nodes)
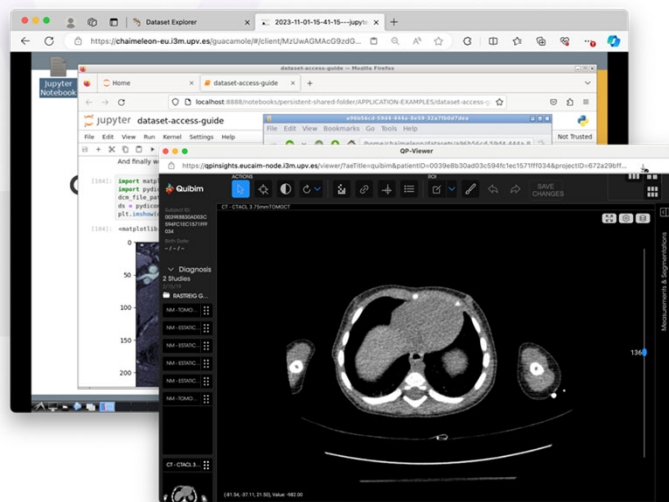
Resource Outputs
(@SPEs or Fed processing)

European Cancer Imaging Initiative – where are we?

Accelerating the development of AI-based cancer imaging and management solutions, empowering scientific and innovative breakthroughs that will shape the future of patients with cancer.

9 cancer types
breast, colon, lung, prostate, rectum, liver, glioma, neuroblastoma, DIPG

1 Central Hub in Operation for Research & Innovation

3 Federation processing demonstrators released

2,500 Hyperontology terms extending the Health DCAT-AP scheme.

EUCAIM Deployment production & development

2 Reference Nodes as Central storage with SPE (480 cores, 15 GPUs)

57 public datasets catalogue Tier1 (*42,000 subjects, 300,000 image series*)

27,000 Tier2 studies within the **federated search service.**

50 dockerized AI tools within the experimentation platform

8 Central Core Services: registry, federated search, access negotiation, helpdesk, training, monitoring, LS-AAI, dashboard

86 registered users with Access Rights to the services. Participation Rules released.

3 levels of compliance as Participation Rules using EUCAIM's mCODE data model.

EUCAIM project space set at OpenEBench
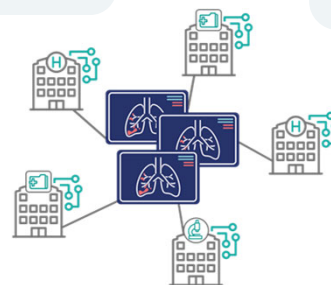
Available at **cancerimage.eu**

European Commission

European Cancer Imaging Initiative – value creation

- **Hybrid Model** - data maintained locally or federated, enhancing ethical standards and privacy

- **Large Partners network engagement**

- **Centralized Access** via single point for data search, processing, and analysis, accelerating workflows

- **Capacity Building** enabling storage of valuable data, and/or access advanced data processing and analysis tools

- **Data Interoperability** enhancing data usability across different common data models and ontology

- **Compliance and Certification** adhering to legislative and ethical standards

- **Benchmarking and validating tools** facilitating the creation of a critical mass for evidence-based medicine

- **Trust and Transparency** strategies ensuring reliability, performance, and safety

- **Support for Regulatory Bodies,** providing certified licensed datasets and tools.

EUCAIM and Medical Devices complying with MDR and AI Act
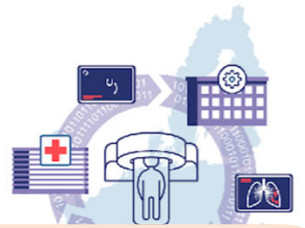
EUCAIM Will transform the creation of medical devices in Europe

<u>What does EUCAIM provide to accelerate the innovation process?</u>

- High-availability, cyber-secure technical infrastructure with technical and organizational information security measures.
- Datasets with data interoperability standards.
- Integration with multi-modal clinical data: EHR, pathology and molecular biology, among others.
- Audit trail mechanism aligned with EU HTA Regulation.
- **For model training:** Allowing data download with license agreements. The manufacturing process requires the availability of data from the manufacturer to train AI models in auditable and traceable infrastructures (AI act).
- **For model validation:** Integration of AI modules in docker containers on the platform, complying with EUCAIM requirements for validation.

Contracts and key documents

- Incorporation agreement and internal bylaws
- Data Exchange contracts
- Data processing assignment agreements
- Platform Terms and Conditions of Use
- Data Access and use policy
- License agreements
- Agreements with critical suppliers

AI Act

AI-based medical software

AI decisions with significant effects

AI medical software with significant automated decision-making

MDR

Automated medical decisions

GDPR

European Commission
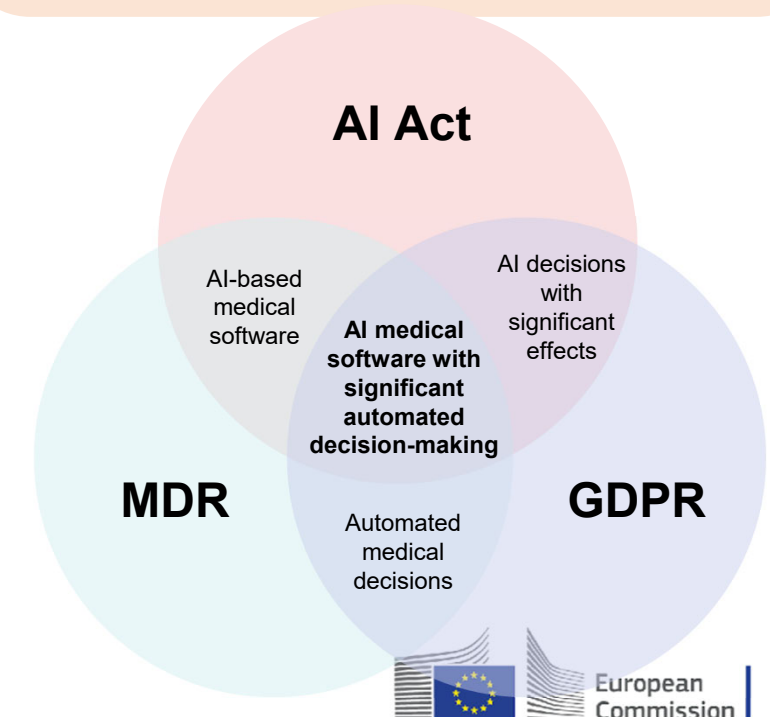
European Cancer Imaging Initiative – business model

11 Member States contributing to the EUCAIM EDIC pre-notification as active members of the EDIC Working Group (every 2 months).

SPAIN
Coordinating country

LATVIA

PORTUGAL

FRANCE

CROATIA

ITALY

GREECE

LITHUANIA

NORWAY

CZECH REPUBLIC

GERMANY

EUCAIM's delegation present at the WG

Netherlands

Poland

Sweden

European Commission

THANK YOU!

VISIT OUR WEBSITE FOR MORE

CANCERIMAGE.EU
LINKEDIN.COM/SHOWCASE/CANCERIMAGE

CONTACT@CANCERIMAGE.EU
STAKEHOLDERS@CANCERIMAGE.EU

#euCancerImaging
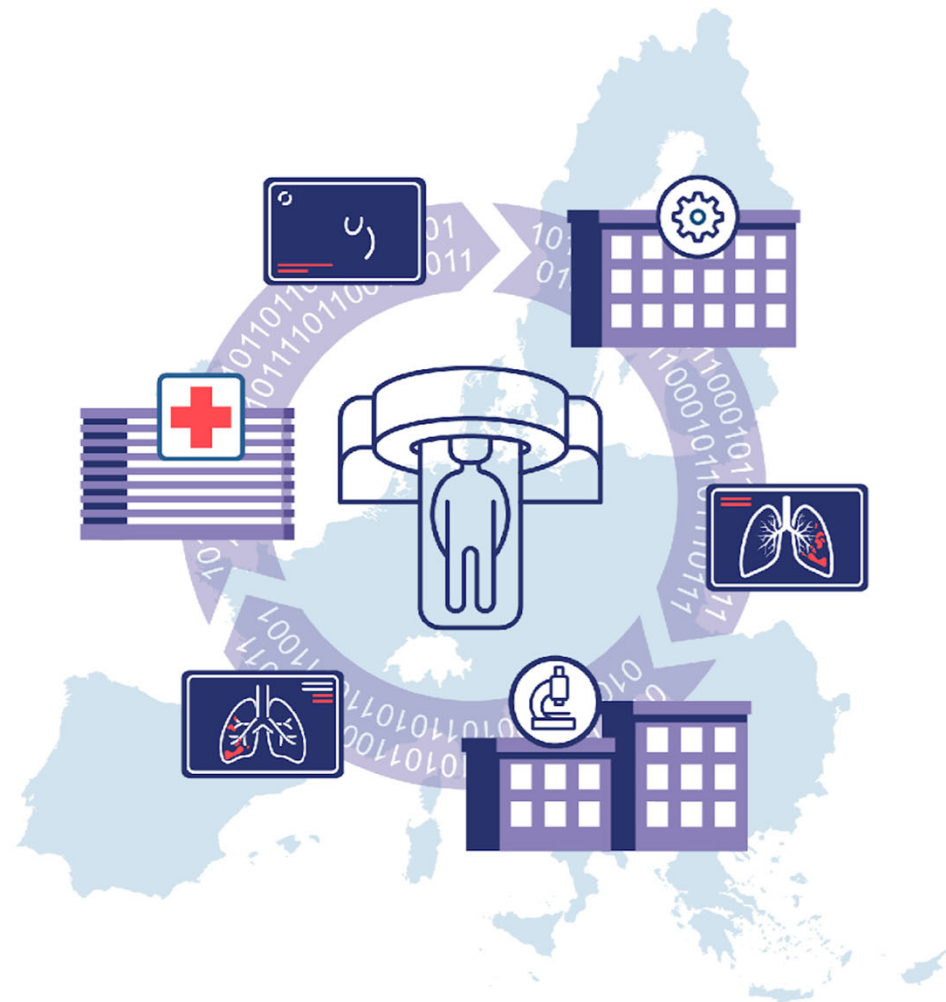
Data Spaces Symposium

GDI – Providing a cross-border federated network
of national human genomic collections

Juan Arenas
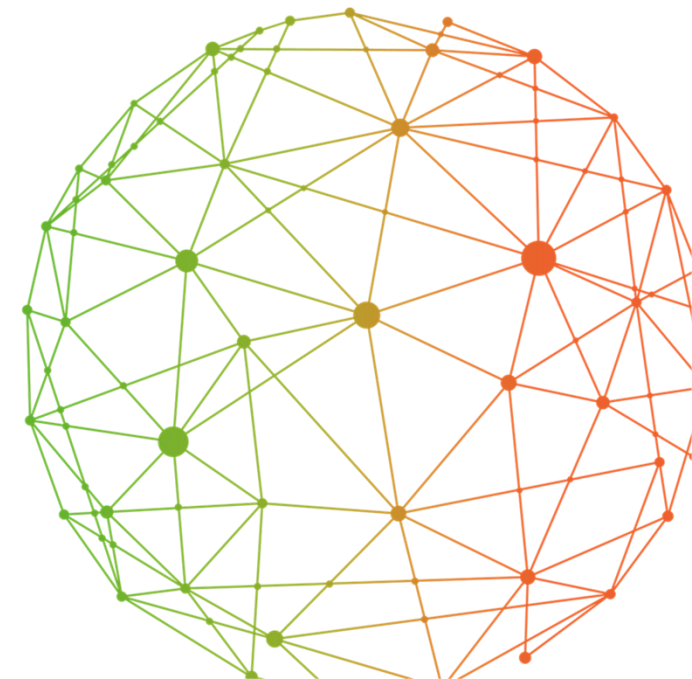
European Genomic Data Infrastructure (GDI)

Overview

Juan Arenas Márquez
Head of ELIXIR Project Management Office &
GDI Deployment Lead
12 Mach 20234 - DSSC
juan,arenas@elixir-europe.org

GDI website

@GDI_EUproject

/company/gdi-euproject

1+MG

Austria
Belgium
Bulgaria
Croatia
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Italy
Latvia
Lithuania
Luxembourg
Malta
Netherlands
Norway
Portugal
Romania
Slovenia
Spain
Sweden

Observer countries

29 countries are working **towards the realisation of personalised medicine to benefit everyone** by providing:

Secure access to

high-quality genomics

& corresponding clinical data

across Europe

for **better research, innovation, personalised healthcare and health policy making**

GDI Project: building the 1+MG data infrastructure

WP1 - Project coordination & support

Make sure it gets done	Genome of Europe

Pillar 1 — **Make it last**

EDIC Model supported by 19 Countries
Statutes being drafted

Genome EDIC as Authorised participation in EHDS & supporting Health Data Access Bodies

Pillar 2 — **Make it work**

Technical demonstrators (EHDS compliant):
- Discoverability (catalogue and record level)
- Access (Governance)
- Distributed processing (SPE)

Pillar 3 — **Make it useful**

Demonstrators of clinical utility for Cancer and Infectious diseases

Federated processing demonstrator for analytics (June 2025) and learning

Interoperability: EHDS, EUCAIM, UNCAN.EU, …

Latest technical and clinical utility video demonstrators:

https://gdi.onemilliongenomes.eu/news/gdi-technical-infrastructure

Value proposition

Genomics integrated into national **healthcare** systems

Innovation

Evidence

GENOMICS TO BENEFIT ALL

Diagnostics, treatments, personalised medicine approaches, prevention

Evidence
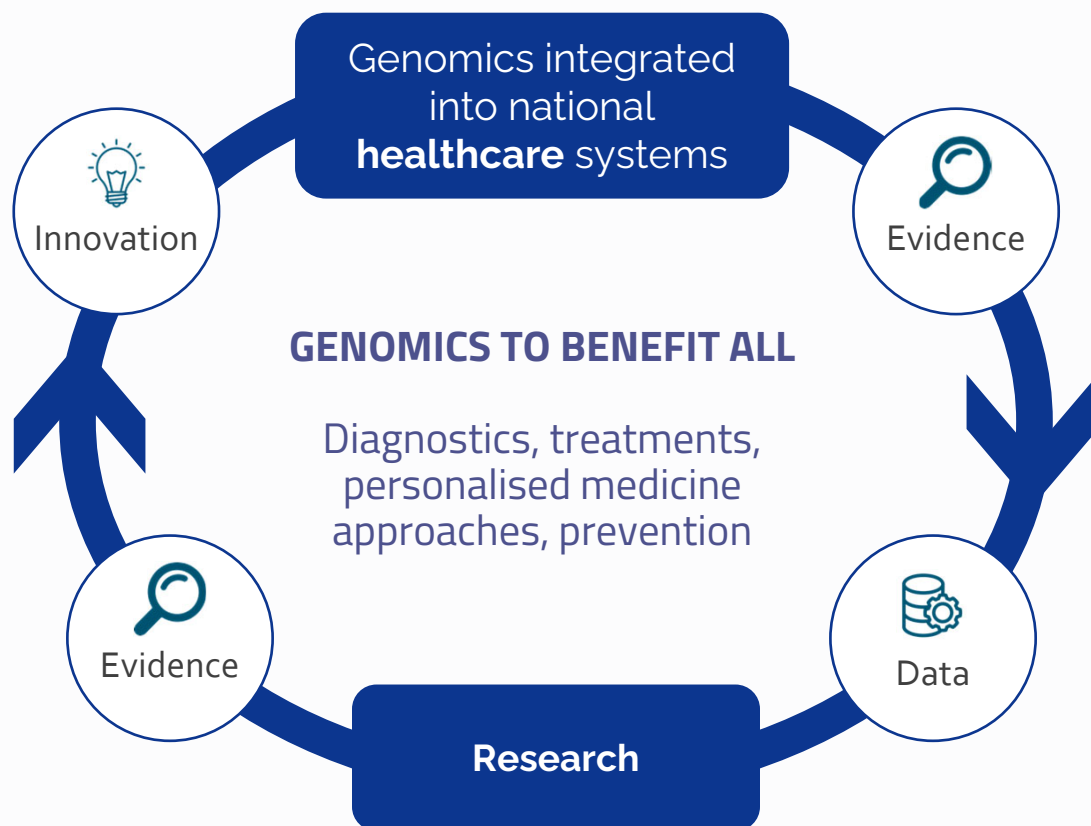
Data

Research

By **unlocking access to high-quality clinical genomics and health data** for secondary use

(High quality genomic and clinical data ⇒ Research ⇒ Knowledge ⇒ Healthcare Innovation)

we will accelerate the deployment of personalised medicine that will significantly **improve prevention, diagnosis and treatment to benefit everyone** in combination with other source of data (e.g. socioeconomic data)

How: https://framework.onemilliongenomes.eu/

User Journey
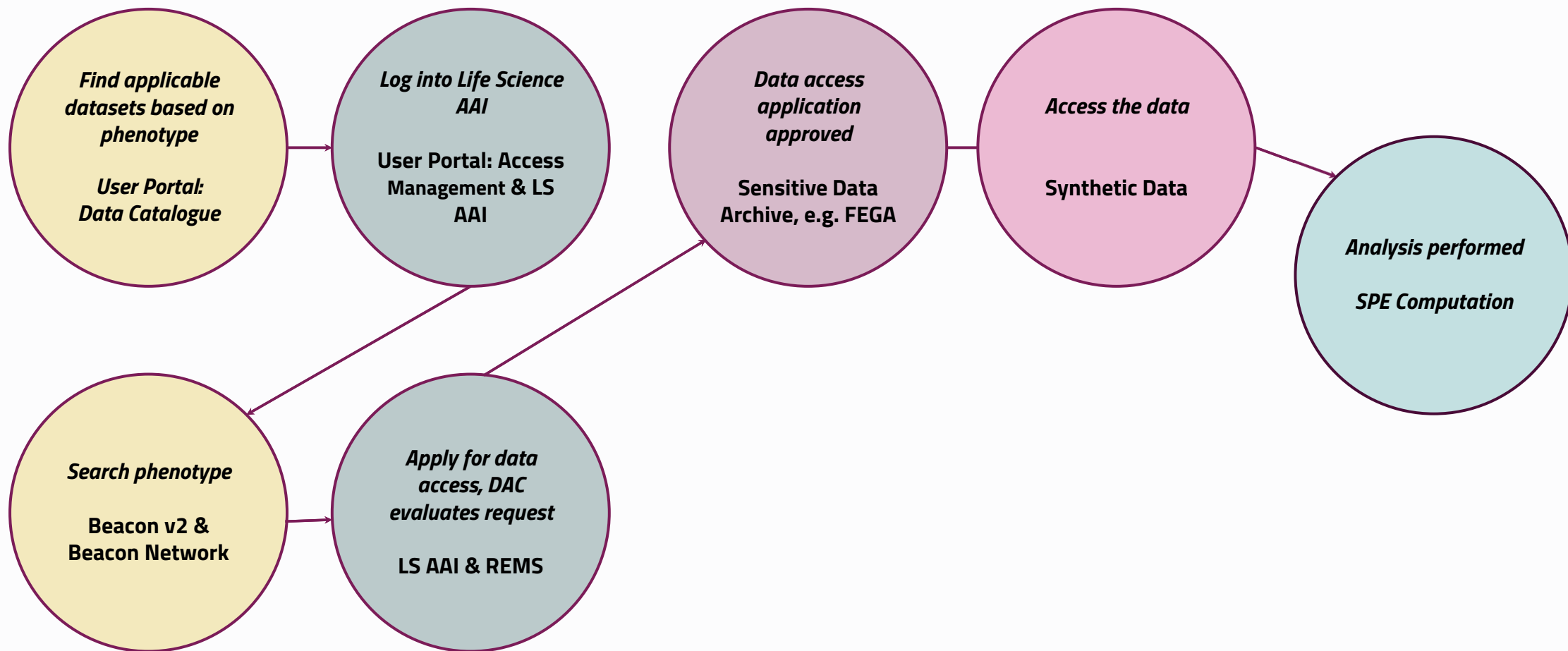
GDI Open source reference implementations - technical implementation

Product	Outline	Prod	PO	Function
Sensitive Data Archive	Securely stores data	✓	Sweden	
LifeScience AAI	Provides a federated Identity	✓	Czechia	
REMS	Allows data access applications and decisions	✓	Finland	
Beacon	Genetic and phenotypic data discovery	✓	Spain	
Beacon Network	Federated network of Beacons	✓	Finland	
Synthetic Data	Artificial anonymous data (1M WGS and Clinical Data0		Finland	
htsget	Secure genetic data distribution		Sweden	
Containerised Computation	Computation via virtualised portable software packages	✓	Czechia	
Federated Computation	Interoperable distributed workflows (analytics & learning)		Spain	
Packaging and Deployment	Packaging and deployment of the starter kit		Spain	
User Portal – Data Catalogue	European level catalogue of data within nodes		Netherlands	
User Portal – Access management	European level application / access management		Luxembourg	

✓ - Product **in production**

European level services

https://github.com/GenomicDataInfrastructure

1+MG / Genome EDIC / EHDS

Authorised Participant

Genome EDIC ← DCAT-AP, eID, eDelivery → HealthData@EU

EU →

integral component of EHDS bringing added value

European connectivity →

across borders interoperable record level discoverability, access and processing

National node →

Support Genome EDIC & HDABs on handling genomic data an associated clinical data

Beacon Network, eID, AAI & Federated Processing

HDABs

Genome EDIC National Node — SPE

Genome EDIC National Node — SPE

Genome EDIC National Node — SPE
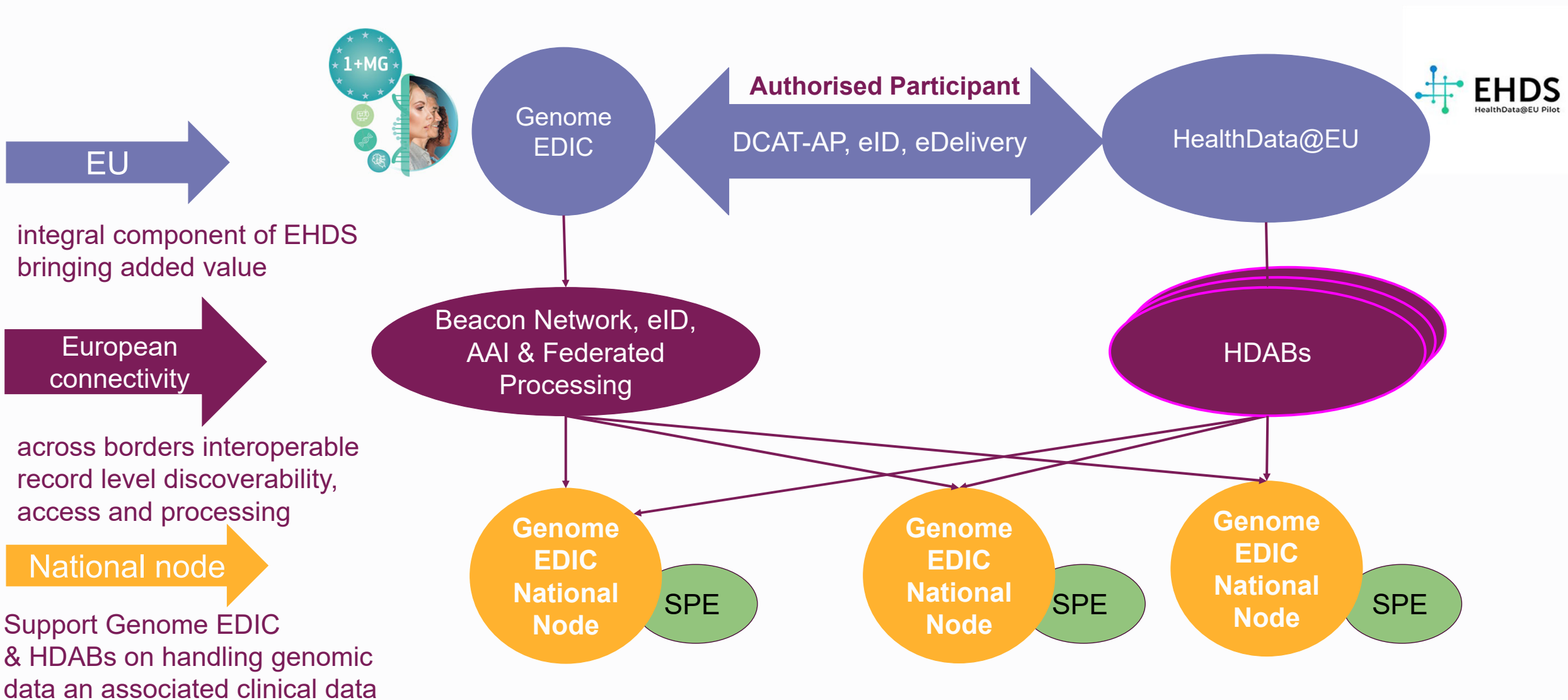
More information

ELIXIR - https://elixir-europe.org

1+MG Initiative - https://digital-strategy.ec.europa.eu/en/policies/1-million-genomes

1+MG Framework - https://framework.onemilliongenomes.eu/

GDI project - https://gdi.onemilliongenomes.eu

Demostrators -https://gdi.onemilliongenomes.eu/news/gdi-technical-infrastructure

Stakeholder portal registration - register here

B1MGPlus project - https://b1mgplus.onemilliongenomes.eu/

ELIXIR Bioinformatics Industry Forum (EBIF) - June 2025 - London

**<u>Topic</u>: Federated life science data analysis :
Overcoming challenges for global impact**

We bring together bioinformaticians and technical specialists to explore solutions to major challenges in the data-driven life science sector.

- Free and open event
- Approximately 80 attendees
- A full day event with
    - short presentations
    - roundtable discussions
    - networking opportunities
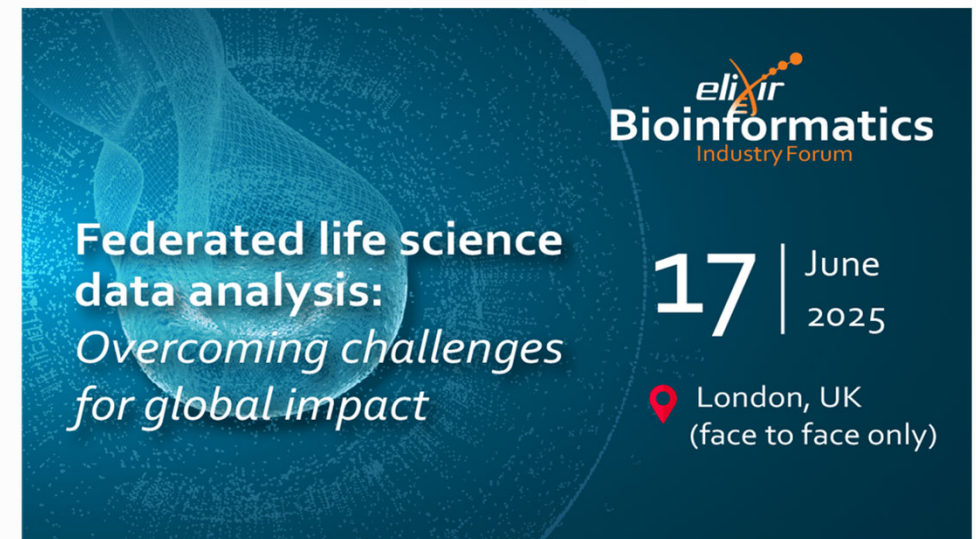
Open for everyone to contribute:

If you are interested in presenting or leading a roundtable discussion email despoina.sousoni@elixir-europe.org.

Data Spaces Symposium

VELES Project & Regional Smart Health Data
Space: Advancing Health Data Sharing

Olga Galanets
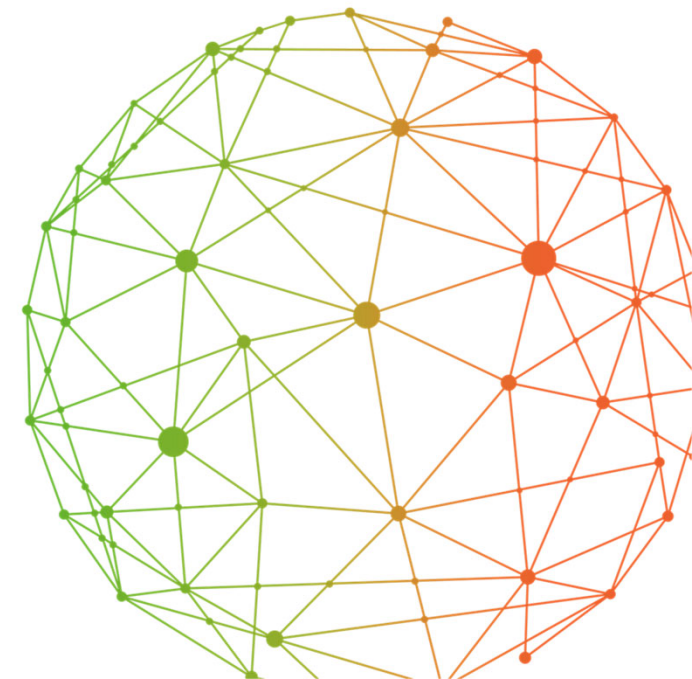
VELES Project &Regional Smart Health Data Space
Advancing Health Data Sharing

Data Spaces Symposium 2025

The Future of Healthcare: unlocking value creation through data sharing

Olga Galanets
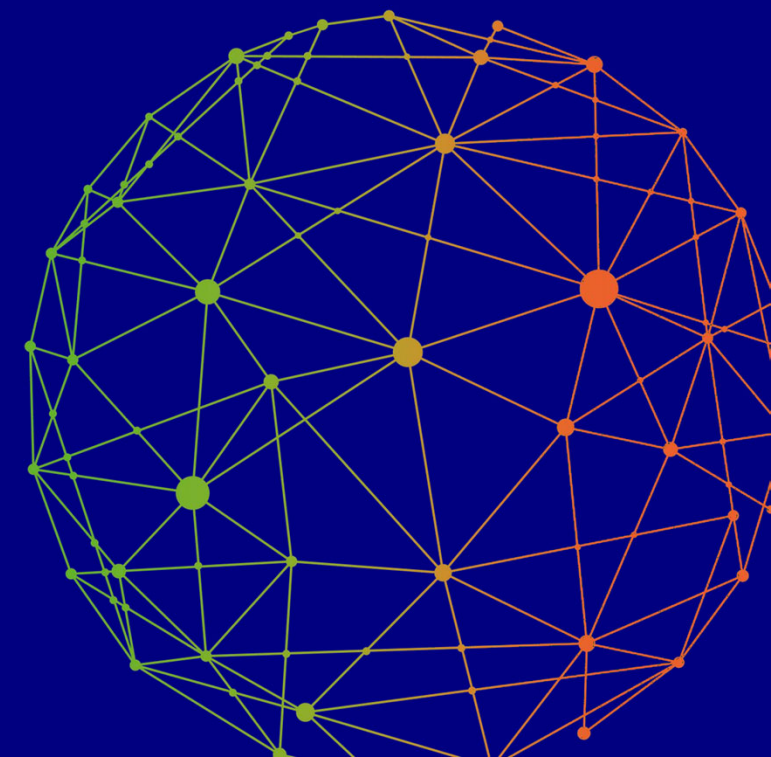
VELES Project Overview

HORIZON-WIDERA-2022-ACCESS-04 Call: Excellence Hubs

Start Date: 1st June 2023
Duration: 4 years

Consortium: 15 Partners from 7 from EU countries, Coordinator: GATE

VELES accelerates the smart health innovation excellence in Bulgaria, Greece, Romania and Cyprus.

VELES creates a sustainable place-based innovation ecosystem, enabled by Regional Smart Health Data Space, including a novel transformational framework, R&I and investment strategy and action plan for development and adoption of innovative and secure digital solutions to underpin the delivery of sustainable healthcare services.

| Industry and practitioners | Citizens | Academia | Policymakers |

Legend (map):
- 1-Greece
- 1-Cyprus
- 1-Romania
- 1-Bulgaria
- 2-Germany
- 2-Spain
- 2-Sweden
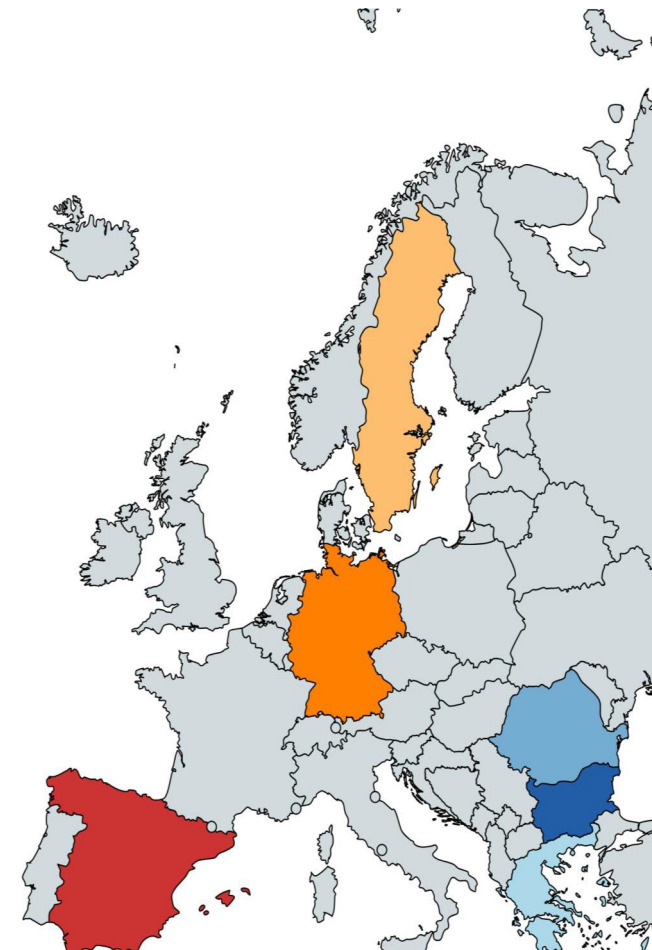
VELES Project: Driving the Future of Smart Health Data Spaces

Developing a Regional Smart Health Data Space (RSHDS) Framework

- Enhancing health data sharing at national &regional levels.
- Improving clinical practices, patient privacy, and secure digital health services.

Demonstrated Through 4 Key Pilots

- Alzheimer's (Bulgaria) |Cerebral Tumors (Romania) |Cancer Treatment (Greece) |Dementia Care (Cyprus)
- Showcasing AI-driven healthcare efficiency &decision-making improvements.

Supporting Cross-Border Healthcare &Personalized Treatments

- Secure data exchange for better patient outcomes.
- Ethical, legal, governance, and business best practices.

Aligned with the European Health Data Space (EHDS)

- Strengthening EU-wide health data integration &collaboration.

Advancing AI-Driven Healthcare

- AI-powered diagnostics, treatment, and patient care improvements.

Scaling &Expanding

- Increasing RSHDS adoption &integrating with EU health initiatives (Horizon Europe).

Advancing Health Data Sharing with IDS-RAM v.5 & Dataspace protocol

Key Benefits & Features

Trust-Based Data Sharing

- Standardized framework enabling secure &controlled data exchange.
- Decentralized environments where hospitals, AI developers, pharma, and researchers retain data control.

Regulatory Compliance &Governance

- GDPR, HIPAA &ethical AI compliance ensured.
- Smart contracts &policies define data usage, access, and monetization.

Seamless Interoperability

- FHIR &HL7 standards enable cross-system data exchange.
- Connects EHRs, IoT devices, AI models, &research databases.

Zero-Trust Security &Encryption

- Decentralized Identity (DID) &Verifiable Credentials (VC) for authentication.
- Confidential Computing &Homomorphic Encryption for secure processing.

AI-Driven Data Utilization

- **Federated Learning** allows AI model training without moving raw patient data.
- **Edge AI &On-Premise Processing** enhance data security.

Transforming Healthcare with Secure & Decentralized Data Spaces

By integrating **IDSA RAM v.5** and **Dataspace protocol**, the healthcare industry ensures **trustworthy, decentralized, and privacy-preserving** health data ecosystems - driving AI-powered medical innovations and secure global collaborations while maintaining **data sovereignty & compliance**.

Status of the Project

1

2

3

Implementation Phase:

- Developing a Regional Smart Health Data Space (RSHDS) Framework for Southeast Europe

Pilot Studies:

- Cancer Treatment (Greece): Data- driven approaches for therapy optimization
- Dementia Treatment (Cyprus): AI- assisted pain assessment tools
- Two additional pilots in Southeast Europe focusing on clinical decision-making

Partnerships:

- Collaboration with hospitals, research institutions, and EU stakeholders

Value Creation of the Project (Business Model & Beyond)

VELES

1. Healthcare Innovation:

AI-driven personalized medicine and predictive healthcare

2. Research &Development:

Enabling data-driven discoveries in medical research

3. Public &Private Collaboration:

Strengthening cross-sector engagement in digital health

5. Economic Impact:

Cost savings in healthcare through efficient data utilization

4. Patient Empowerment:

Providing individuals with control over their health data

1 2 3 4 5

Data Spaces Symposium

Getting ready for the EHDS: The IDERHA Dataspace and our plan to align with the latest EHDS requirements

Anja Burmann
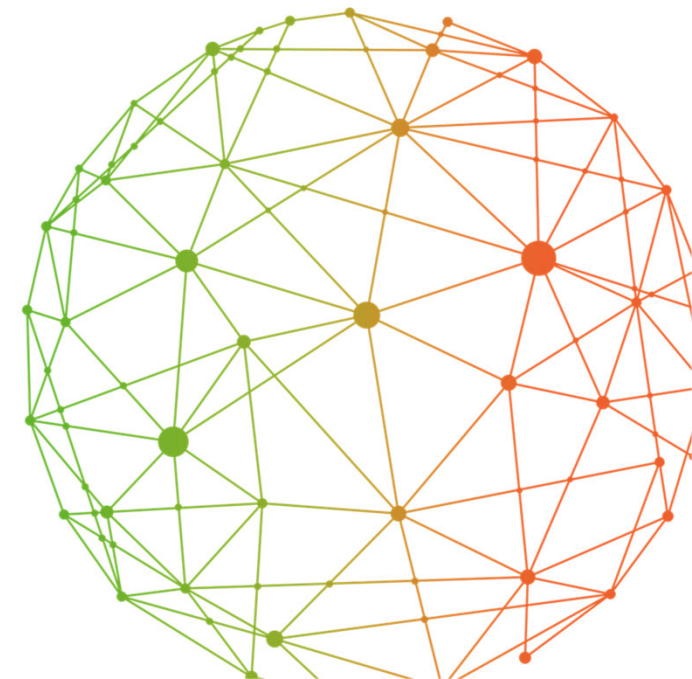
Getting ready for the EHDS: The IDERHA Data Space

A public private Partnership to leverage healthcare data

Data Spaces Symposium 2025
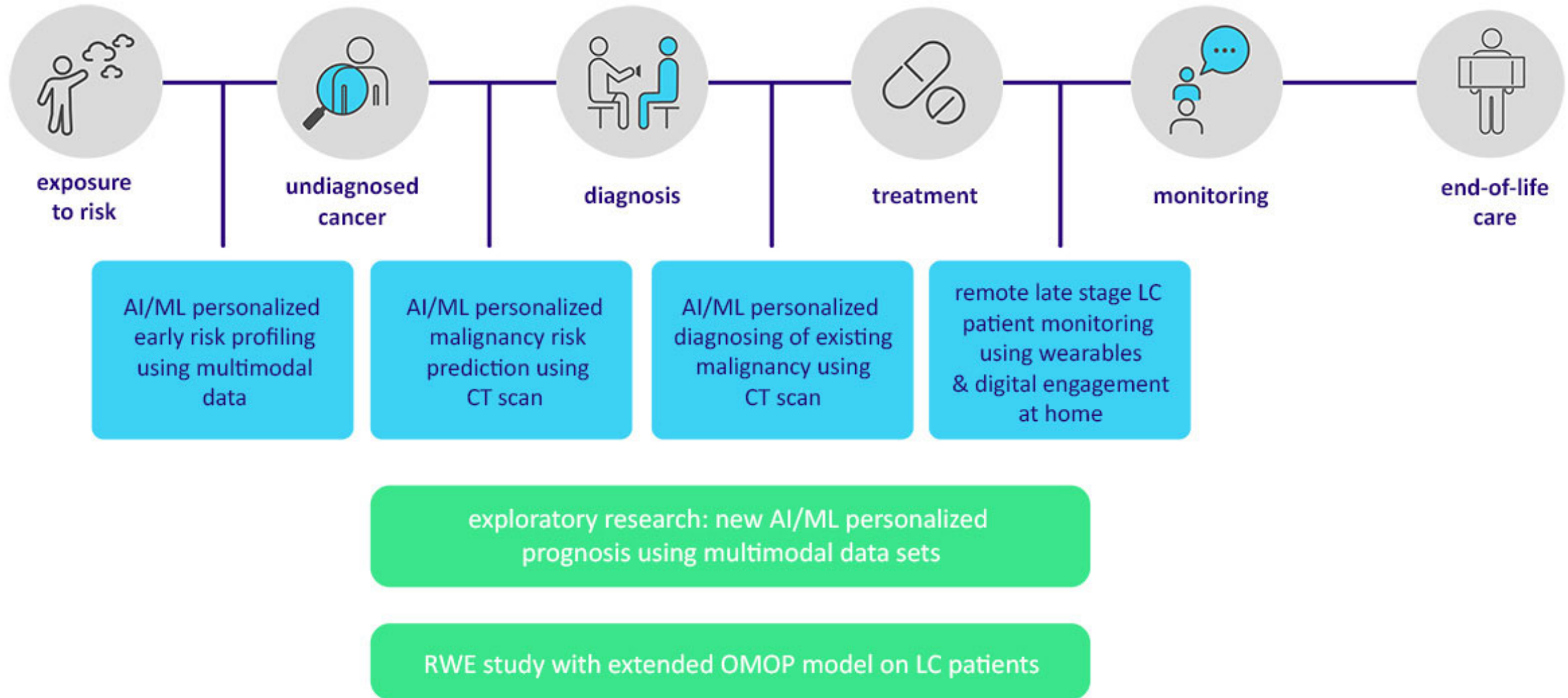
33 Leading Expert Partners from 10 Countries in Europe, plus strong non-EU support

academia & research & public

LUDWIG BOLTZMANN INSTITUTE
Digital Health and Prevention

FH University of Applied Sciences
TECHNIKUM WIEN

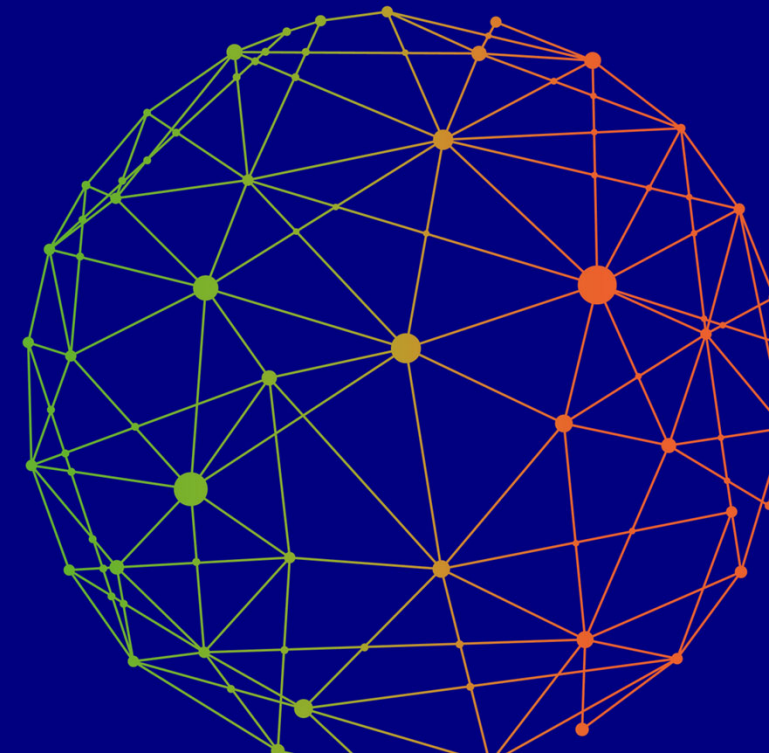iHD The European Institute for Innovation through Health Data

ITTM
Information Technology for Translational Medicine

uni.lu | LCSB

MEDICAL UNIVERSITY OF VIENNA

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

DEFACTUM

Q

Fraunhofer

MSB Medical School Berlin
Hochschule für Gesundheit und Medizin

VTT

European Cancer Patient Coalition

SERVICIO ANDALUZ DE SALUD
Consejería de Salud y Consumo

EPF European Patients Forum

lygature
pioneering medicine. together.

IIS La Fe
Health Research Institute

ASKLEPIOS

MRI Klinikum rechts der Isar Technische Universität München   TUM

SERVIZO GALEGO DE SAÚDE

industry & SM

Johnson&Johnson

Johnson&Johnson MedTech

PHILIPS

Takeda

sanofi

labcorp

Roche

associated

ERS EUROPEAN RESPIRATORY SOCIETY
every breath counts

hygiaso

LUCE Lung Cancer Europe

NICE National Institute for Health and Care Excellence

affiliated

Junta de Andalucía
Consejería de Salud y Consumo
Fundación Pública Andaluza para la Gestión de la Investigación en Salud de Sevilla (FISEVI)

IDERHA
integrating health data

1. Access to diverse data at scale

2. Further develop a scalable, open platform

3. Tools focused on needs of Patients, Clinicians & Research

4. Shape Policy
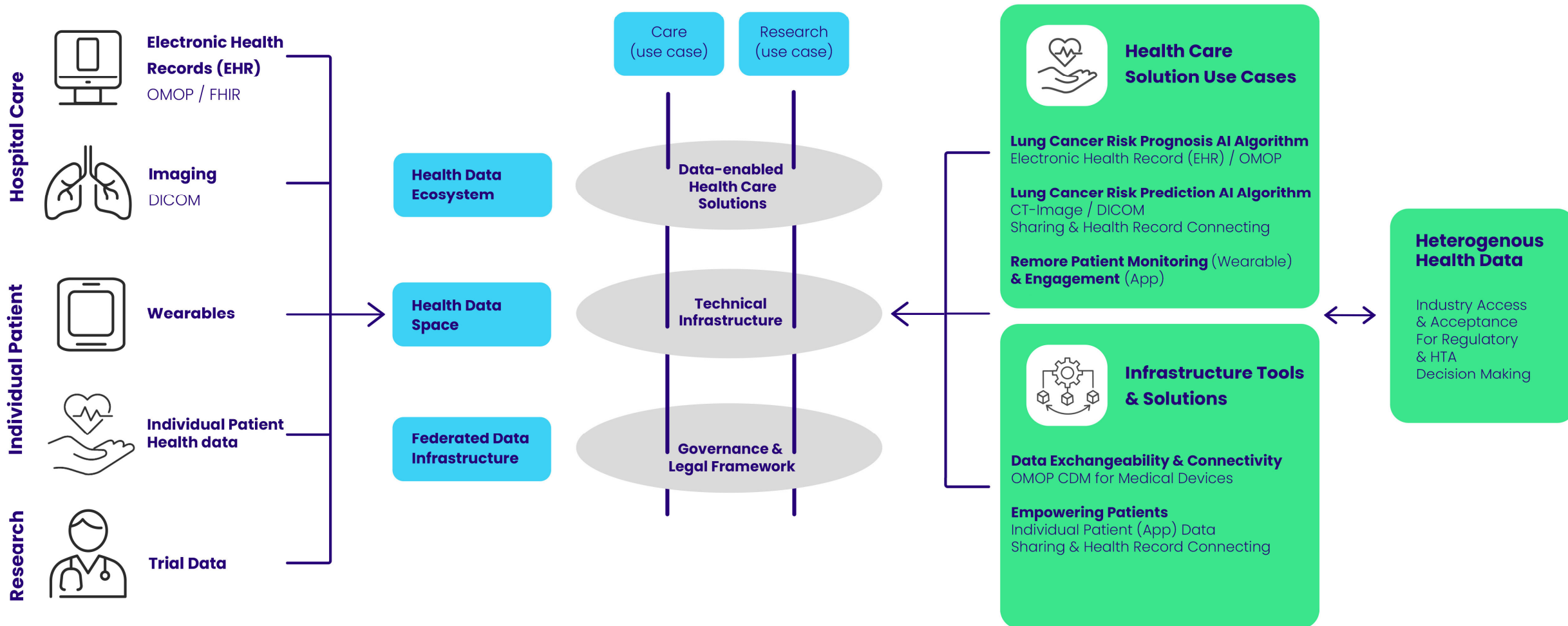
Hospital Care

Electronic Health Records (EHR)
OMOP / FHIR

Imaging
DICOM

Individual Patient

Wearables

Individual Patient Health data

Research

Trial Data

Health Data Ecosystem

Health Data Space

Federated Data Infrastructure

Care (use case)

Research (use case)

Data-enabled Health Care Solutions

Technical Infrastructure

Governance & Legal Framework

Health Care Solution Use Cases

Lung Cancer Risk Prognosis AI Algorithm
Electronic Health Record (EHR) / OMOP

Lung Cancer Risk Prediction AI Algorithm
CT-Image / DICOM
Sharing & Health Record Connecting

Remore Patient Monitoring (Wearable) **& Engagement** (App)

Infrastructure Tools & Solutions

Data Exchangeability & Connectivity
OMOP CDM for Medical Devices

Empowering Patients
Individual Patient (App) Data
Sharing & Health Record Connecting

Heterogenous Health Data

Industry Access & Acceptance For Regulatory & HTA Decision Making

www.IDERHA.org

IDERHA
integrating health data

IDERHA SPE Architecture Principle

Based on standards, enabling interoperability & easy re-use of existing solutions incl. FAIR, GA4GH* & IDSA**
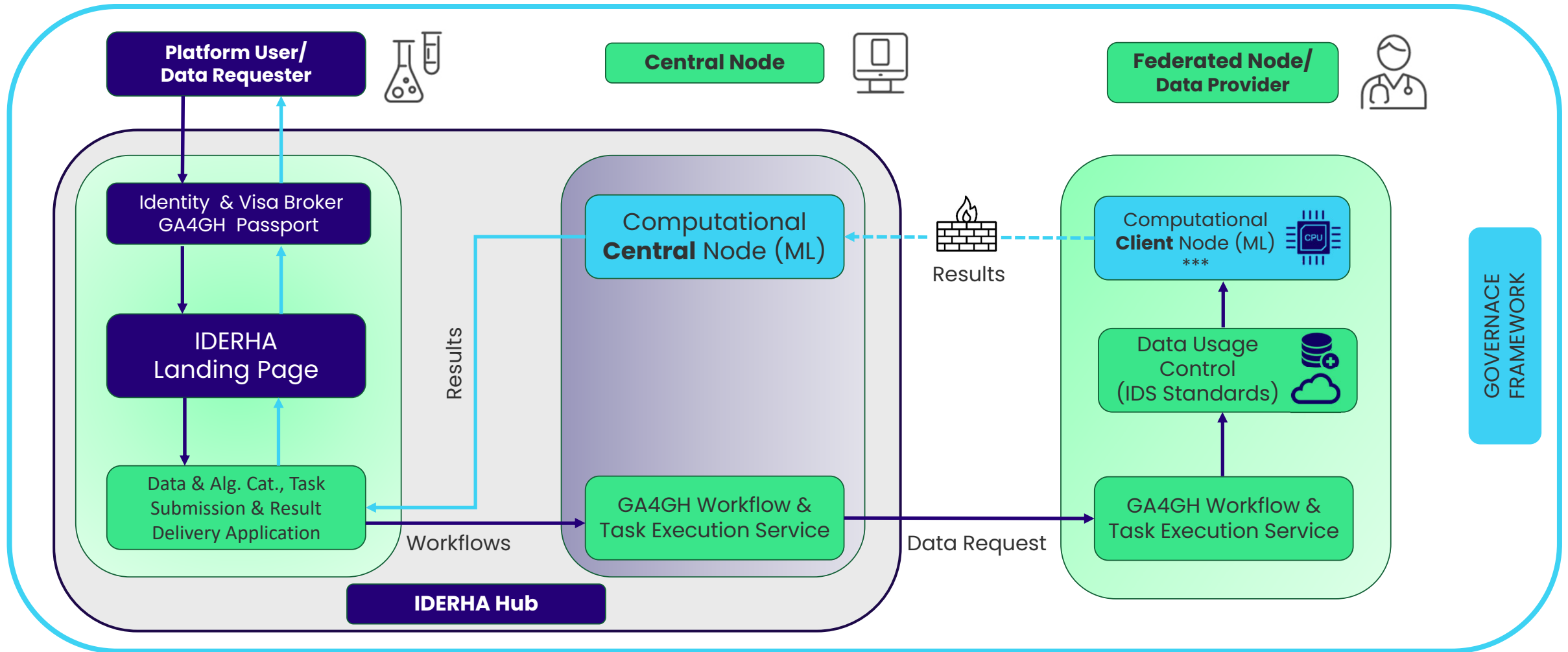
Platform User/ Data Requester

Central Node

Federated Node/ Data Provider

Identity & Visa Broker GA4GH Passport

IDERHA Landing Page

Computational **Central** Node (ML)

Results

Computational **Client** Node (ML) ***

CPU

Results

Data Usage Control (IDS Standards)

GOVERNACE FRAMEWORK

Data & Alg. Cat., Task Submission & Result Delivery Application

GA4GH Workflow & Task Execution Service

GA4GH Workflow & Task Execution Service

Workflows

IDERHA Hub

Data Request

IDERHA
integrating health data

IDERHA aligns public-private partnerships with the European Health Data Space Principles
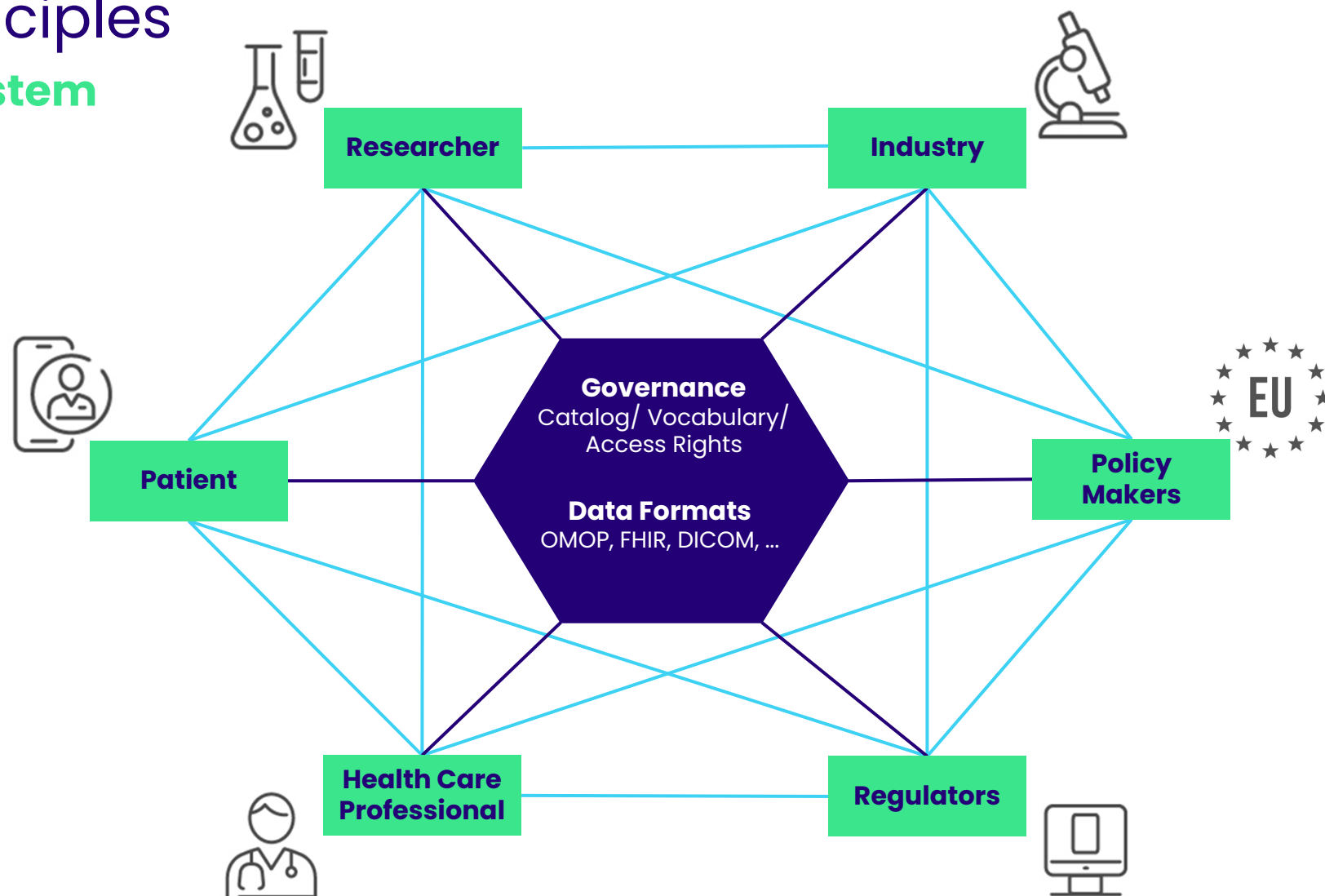
Builds health-specific ecosystem
- Rules
- Common standards + practices
- Infrastructures
- Governance framework

Empowers individuals
- Increased access and control
- Support free movement
- Market for EHRs

Enables health data reuse
- Consistent
- Trustworthy
- Innovation support
- Policy making
- Regulatory activities

Researcher

Industry

Patient

Governance
Catalog/ Vocabulary/
Access Rights

Data Formats
OMOP, FHIR, DICOM, …

Policy Makers

EU

Health Care Professional

Regulators

IDERHA
integrating health data

Thank you, let's get in touch!

Contact

Dr. Anja Burmann

Head of Department Healthcare

Fraunhofer ISST

Speicherstr. 6

D-44147 Dortmund

www.isst.fraunhofer.de/en
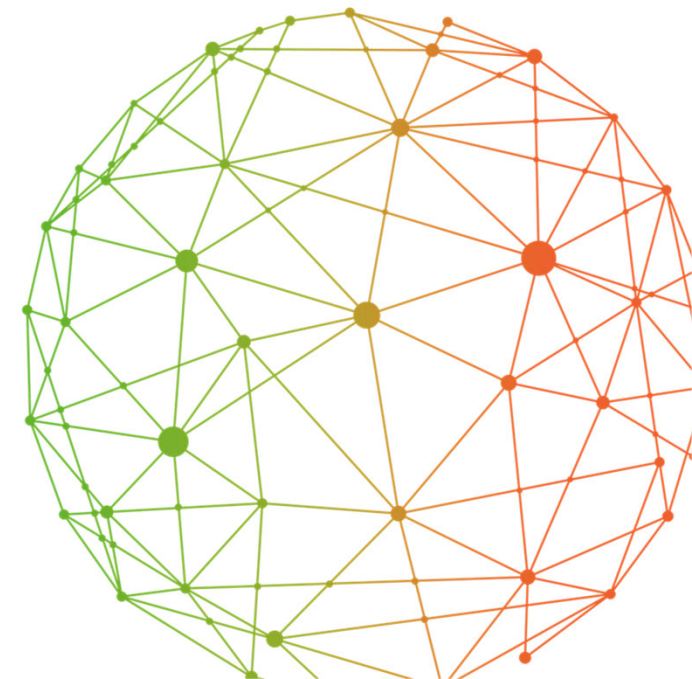
https://www.linkedin.com/in/anja-burmann/
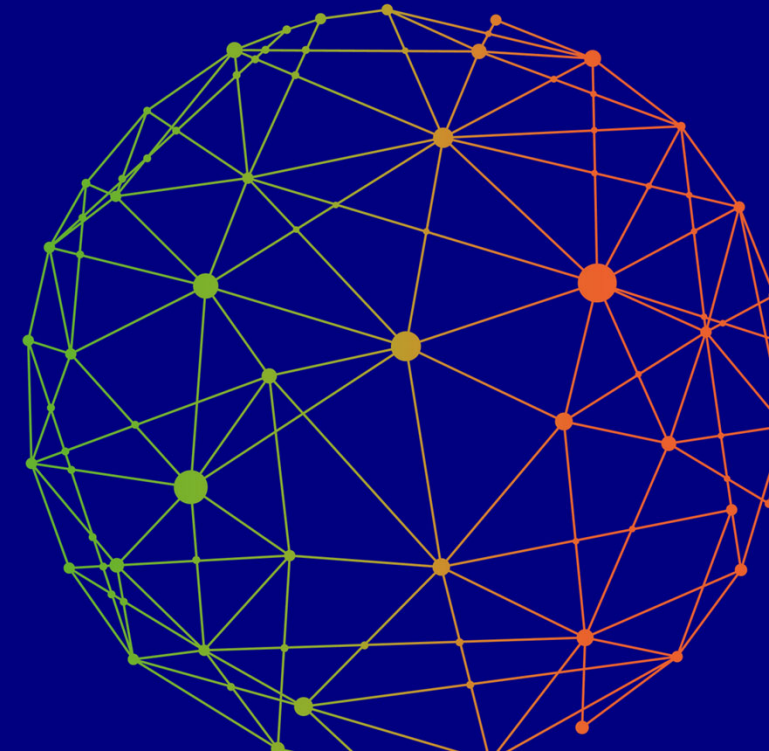
Data Spaces Symposium

The Future of Healthcare: Unlocking Value
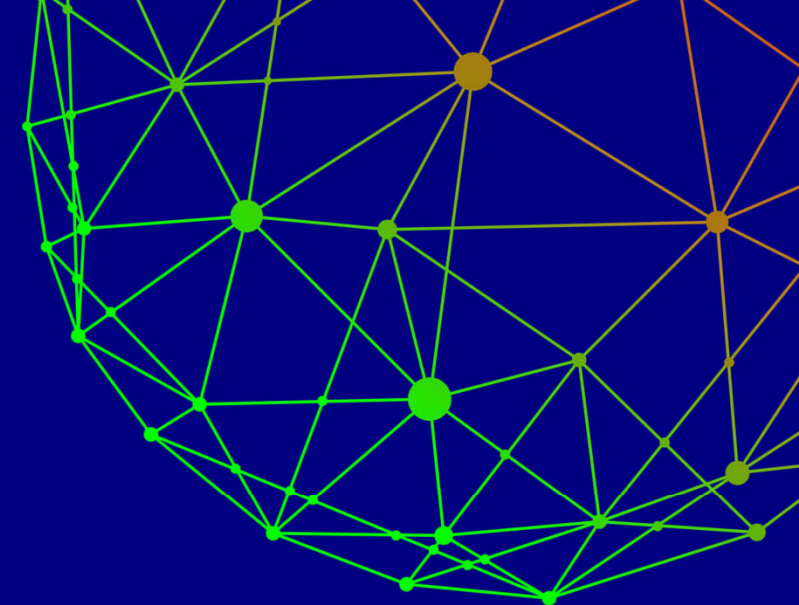Creation Through Data Sharing

Marta Musidlowska, Juan Arenas, Maciej Bobowicz,
Anja Burmann, Olga Galanets, Irena Pavlova

Data Spaces Symposium

Share data. Unlock value. Boost impact.

Panel discussion | The future of healthcare:
Unlocking Value Creation Through Data Sharing

Marta Musidlowska
KU Leuven

Juan Arenas
Elixir

Maciej Bobowicz
Gdansk Medical
University

Anja Burmann
Fraunhofer ISST

Olga Galanets
IDSA

Irena Pavlova
GATE

Data Spaces Symposium

Enjoy your lunch!

These are the sessions you can choose from at 13:30:

Track 1:

Focus session on telcos & ICT providers

Key role of telcos and ICT providers: Enabling data spaces and providing infrastructures

Track 2:

Domain session on smart cities and communities

Societal impact of data spaces: addressing local challenges, deliverering better services to citizens

Track 3:

Data space tech session

Capabilities you need to make a data space a success